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NOTICE OF ALLOWANCE AND ISSUE FEE DUE

HM42/0601
SUGHRUE MION ZINN MACPEAK & SEAS
2100 AVENUE NW
WASHINGTON DC 20037-3202

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/860,377	08/28/97	007	MORRIS, P 1612	04/16/99
First Named Applicant	TAKEUCHI,	MAKOTO		

TITLE OF INVENTION: QUINUCLIDINE DERIVATIVES AND MEDICINAL COMPOSITION THEREOF (AS AMENDED)

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
045752	514-305.000	R93	UTILITY	NO	$1210.00	07/16/99

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

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IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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NOTICE OF ALLOWANCE AND ISSUE FEE DUE

HM12/0416
SUGHRUE MION ZINN MACPEAK & SEAS
2100 AVENUE NW
WASHINGTON DC 20037-3202

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/860,377	08/28/97	007	MORRIS, P 1612	04/16/99

First Named Applicant: TAKEUCHI, 35 USC 154(b) term ext. = 0 Days.

TITLE OF INVENTION: L. QUINUCLIDINE DERIVATIVES AND MEDICINAL COMPOSITION THEREOF

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1 045752	514-305.000	R93	UTILITY	NO	$1210.00	07/16/99

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UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/860,377	08/28/97	TAKEUCHI M	Q45752

HM12/0416
SUGHRUE MION ZINN MACPEAK & SEAS
2100 AVENUE NW
WASHINGTON DC 20037-3202

EXAMINER	
MORRIS, P	
ART UNIT	**PAPER NUMBER**
1612	17

DATE MAILED: 04/16/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

NOTICE OF ALLOWABILITY

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

☒ This communication is responsive to Paper no. 16 filed 3-31-99.

☒ The allowed claim(s) is/are 1, 3-6, 8 and 9 (renumbered as 1-7).

☐ The drawings filed on _____ are acceptable.

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE **THREE MONTHS** FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☐ Applicant MUST submit NEW FORMAL DRAWINGS

☐ because the originally filed drawings were declared by applicant to be informal.

☐ including changes required by the Notice of Draftperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. _____.

☐ including changes required by the proposed drawing correction filed on _____, which has been approved by the examiner.

☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftperson.

☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☐ Interview Summary, PTO-413

☐ Examiner's Amendment/Comment

☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

☐ Examiner's Statement of Reasons for Allowance

PATRICIA L. MORRIS
PRIMARY EXAMINER
GROUP 120

☆ U.S. GOVERNMENT PRINTING OFFICE: 1997—429-299

No enablement is shown for the treatment and prevention of all urinary diseases. The tests set forth on pages 23-27 of the specification are insufficient to support the claims for the treatment and prevention of any and all urinary diseases.

The disclosure provides no indication of whether the compounds present some disease, reverse, arrest or retard the course of any disease, or even alleviate some the symptoms of the disease.

As pointed out in In re Schmidt, 377 F.2d 639, 153 USPQ 640 (CCPA 1967), lack of specificity about the medicinal properties and specific effects of claimed compounds is not outweighed by a detailed "boiler plate" recitation of conventional techniques limited to the manner in which the compounds may be formulated and administered. The disclosure must inform those skilled in the art how to use the invention, not merely invite them to find out for themselves how to use it. See also In re Moureu, 345 F.2d 519, 145 USPQ 452 (CCPA 1965).

Issenstead v. Watson, (DCDC 1957) 157 F Supp. 7, 115 USPQ 408 and Schindler v. Comr. of Pats. (DCDC 1967) 269 F Supp. 630, 155 USPQ 838. Noted where an application discloses therapeutic effect on humans or a cure for a human disease as the utility of a claimed process, the District Court held that proof of such utility is required unless one of ordinary skill in the art would accept the utiltiy statement as obviously valid and correct. Radoev v. Brenner, Ferguson, (POBA 1957) 117 USPQ 229.

The Board of Appeals and the CCPA have held that even though the specification does not mention human use specifically, the Patent Office is not precluded from finding an inference of

human use and require proof thereof, when such use is a medical nature for the treatment of a serious disease. Ex parte Moore et al., (POBA 1960) 128 USPQ 8; In re Citron, (CCPA 1964) 325 F.2d 248, 139 USPQ 516; In re Hartop et al., (CCPA 1962) 311 F.2d 249, 135 USPQ 419.

Claims 1-9 are rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms cycloalkyl, cycloalkenyl and aryl, in the A groups, are not limited from infinity in their carbon size in claims 1-4 and 9. Very large hydrocarbons would be waxes, which would make them unacceptable for pharmaceutical preparations.

The expression(s) "which may be substituted by an optional substituent" is employed with considerable abandon throughout the claim 1 with no indication given as to what the substituents really are.

Aryl could be read as aromatic. Some aromatic groups are heterocyclic. Therefore, the indefiniteness of the claims causes overlap.

Applicants claim all aryl radicals in A . Applicants' exemplification cannot be seen to provide adequate representative support for such a claim.

There are no carbon limits on aryl in claims 1-4 and 9.

The definition of aryl is varied, note the footnotes on pages 134 USPQ 301-304 of In re Sus, for multiple varied definitions of aryl.

Therefore, applicants need to indicate in the claims what they intend by aryl.

All aryl radicals are not supported in the specification, yet they are claimed here. Applicants could resolve this point in the claim by indicating aryl is phenyl, naphthyl, or indicate a carbocyclic aryl of 6 to 10 carbon atoms.

A Markush listing of specific intended, producible rings for aryl is suggested in claims 1-4 and 9.

Applicants have been permitted the examination of their pharmaceutical use here, as well. In the pharmaceutical area, declarations under 37 CFR 1.132 are often employed to set forth the advantage of a particular substituent. The definition and claiming of substituents is extremely important in the claims of the application. Applicants should not be able to preempt future work of others by means of claims to componds they themselves did not make and test.

One should be able, from a reading of the claims, determine what that claim does or does not encompass.

Why? Because that claim precludes others from making, using, or selling that compound for 20 years. Therefore, one must know what compound is being claimed.

Assuming that applicant is claiming what he regards as his invention, there are in reality only two basic grounds for rejecting claim under 35 U.S.C. 112, first is that language used is not precise enough to provide clear-cut indication of scope of subject matter embraced by claim; this ground finds it basis in second paragraph of section 112; second is that language is so broad that it causes claim to have a potential scope of protection beyond that which is justified by

specification disclosure; this ground stems from first paragraph of section 112, merits of language in claim must be tested in light of these two requirements; In re Swinehardt & Sfiligo, (CCPA) 169 USPQ 226.

The unknown substitution and aryl variables are not believed to meet the requirements of 35 USC 112, first and second paragraph. These unknown substituents and aryl groups could easily alter the utility.

The written description is considered inadequate here in the specification. Conception of the intended substituents and aryl groups should not be the role of the reader. Applicants should, in return for a 20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 USC 112, first and second paragraph. If you (the public) find that it works, I claim it, is not a proper basis of patentability. In re Kirk, 153 USPQ 48, at page 53.

The claims measure the invention. United Carbon Co. V. Binney & Smith Co., 55 USPQ 381 at 384, col. 1, end of 1st paragraph, Supreme Court of the United States (1942).

The U.S. Court of Claims held to this standard in Lockheed Aircraft Corp. v. United States, 193 USPQ 449, "Claims measure invention and resolution of invention must be based on what is claimed".

The C.C.P.A. in 1978 held "that invention is the subject matter defined by the claims submitted by the applicant. We have consistently held that no applicant should have limitations of

the specification read into a claim where no express statement of the limitation is included in the claim": In re Priest, 199 USPQ 11, at 15.

Claim 1 fails to clearly claim what is intended by applicants. Claim 8 provides evidence that optical isomers are intended. However, claim 1 does not recite that optical isomers are intended.

Claim 8 is rejected under 35 U.S.C. 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

No antecdent basis can be found for optically active substances in claim 1.

Allowable Subject Matter

Claims 1 and 9 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, set forth in this Office action and rewritten directed solely to the elected subject matter.

Claims 2-8 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112,set forth in this Office action and to include all of the limitations of the base claim and any intervening claims and rewritten directed solely to the elected subject matter.

Conclusion

Claims 12 and 13 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Morris whose telephone number is (703) 308-4533.

PATRICIA L. MORRIS
PRIMARY EXAMINER
GROUP 120

plm

July 13, 1998